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DEVELOPMENT OF A BLOOD-PRESSURE TRANSDUCER FOR THE TEMPORAL ARTERY

by G. L. Pressman and P. M. Newgard

Prepared under Contract No. NAS 2-1332 by STANFORD RESEARCH INSTITUTE Menlo Park, Calif.

for

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ABSTRACT

This report describes three phases of research on the direct force method of externally measuring arterial blood pressure. First, a miniaturized transducer was designed specifically for application on the superficial temporal artery of man. This device incorporated a differential-transformer sensing element with special mounting to reduce response to acceleration. Second, a transducer of earlier design, intended for the radial artery of man and using strain-gauge techniques was extensively tested on experimental animals and compared with direct intra-arterial measurements. Finally, a number of techniques for the sensing of the transducer position over the artery were investigated both theoretically and experimentally.

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I INTRODUCTION AND SUMMARY

A. OBJECTIVES

The objectives of the research reported here were the following:

- To design an indirect blood-pressure transducer for the temporal artery;
- (2) To test the strain gauge model of the transducer on experimental animals; and
- (3) To study techniques for positioning the transducer over the artery.

B. SUMMARY OF RESULTS

1. Design of Temporal Artery Transducer

The design of a temporal artery transducer was the major portion of the project. The design criteria for such a transducer were established in a preceding Contract (NAS 2-809) and are covered in the Final Report for that project.^{1*} Briefly, the criteria are:

- (1) The arterial rider diameter must be less than 0.020 in;
- (2) The rider deflection must be reduced to approximately 3 $\mu in/100$ mmHg; and
- (3) The over-all transducer size, including air box, must be reduced.

In attempting to meet these objectives, a number of design obstacles became apparent. The most important of these were the problem of acceleration sensitivity and the difficulty of obtaining small overall size. In order to approach the design criteria, it was necessary to drop the original concept of a force-balance type of transducer and rely on a diaphragm-suspension, differential-transformer design. This approach

 $[^]st$ References are listed at the end of the report.

permitted minimum mass of the arterial rider, and greatly reduced acceleration response was achieved by suspension of the differential transformer coil, which then acted as a compensation of acceleration forces.

Since it was not possible to obtain commercially a differential transformer of small enough over-all size to satisfy the final criterion, a special unit of 1/8-in diameter by 1/8-in high was constructed by Kavlico Electronics of Van Nuys, California. The stiffness available with this system was 3 μ in/100 mmHg.

Two models of differential transformer transducers were constructed. The first of these used a commercially available large-size differential transformer, and therefore had excessive over-all dimensions in terms of the design goals. This unit was, however, useful in validating the operational concept of the device. With this transducer it was possible to obtain calibrated pulse recordings from the temporal artery. The miniature transducer subsequently built around the Kavlico differential transformer performed in a similar manner, but presented three major areas of difficulty:

- (1) It was not possible to include an adjustment for zero-level core position. The core must be brought as close as possible to the electrical center of the differential transformer by removing the rider and moving the core (which slips over the rider) a minute amount in the direction toward null. Proper null setting of the core permits two improvements in operation: higher amplifier gain without saturation and use of higher excitation frequencies with concomitant increase in transformer sensitivity.
- (2) The excitation voltage must be limited to lv rms.

 This limitation is somewhat offset by a higher sensitivity than that obtainable with the larger differential transformer.

(3) The low impedance of the transformer increases sensitivity to variations in cable and resistance; hence, these components must be carefully designed and handled.

Both transducers show a relatively high electrical noise output with the wideband demodulator system that was used for testing. It is anticipated that in actual use, once optimum operational frequencies are determined, the wideband demodulator can be replaced with one of narrow-band design and additional filtering added to the output signal, thus eliminating a large portion of this electrical noise.

2. Position Sensing Studies

Of the four approaches to position sensing for the transducer studied, only a technique using piezoelectric elements appears feasible. Because of several problems in the design and construction of the miniature differential transformer transducer, no attempts were made to incorporate a position sensor in this device.

3. Testing of Strain Gauge Transducer

Two new models of the strain gauge design developed in the previous project were built and used for testing on laboratory animals. A series of experiments was performed in which the animals were given various drugs to produce wide variations in pulse rate, pulse waveform, and blood pressure. Because there is no superficial artery on a dog large enough for use with this transducer, a portion of the femoral artery was exposed and the transducer placed directly on the artery for these tests. These tests showed that the average deviation from the reading presented on a reference Statham transducer was approximately ±5 percent, if the readings were corrected for temperature variations with a thermistor. One particular transducer, the Model S-5B, was superior in linearity and temperature stability and could match the reference transducer to within ±3 percent. An additional test was performed by Life Sciences Division personnel including some not involved in earlier procedures; this test confirmed the earlier results.

II DIFFERENTIAL TRANSFORMER TRANSDUCER DESIGN

Previous research¹,² had shown that the SRI strain gauge bloodpressure transducer developed under the earlier contract required mofification and refinement to achieve the capability of measuring arterial pressure at the temporal artery. The differential transformer transducer described herein represents an attempt to accomplish these modifications and prove the feasibility of a temporal artery transducer.

A. ARTERIAL RIDER CONSIDERATIONS

The most basic requirement of such a temporal artery blood-pressure transducer is that the arterial rider must be smaller than the diameter of the artery. In the case of the temporal artery of man, this requires a rider dimension somewhat smaller than 0.030 in. Reducing arterial rider size also simplifies positioning of the transducer. In addition, it was determined that the rider should be circular (rather than rectangular as in previous models) to eliminate the problems of orienting the rider length along the axis of the artery.

Several serious design penalties are encountered as one reduces rider size and contact area, due to the attendant reduction in the force being measured. Since the force acting on the rider is the product of blood pressure and rider area, any reduction in rider area results in a proportionate reduction in blood-pressure force. The most serious consequence of a reduction in blood-pressure force is that the transducer becomes more sensitive to inertia forces produced by acceleration of the transducer case. The sensitivity is proportional to a ratio of forces:

Acceleration effect = \frac{\text{inertia forces}}{\text{blood-pressure forces}} = \frac{(\text{suspended mass}) (\text{applied acceleration})}{(\text{blood pressure}) (\text{rider area})}

The suspended mass of the transducer includes the arterial rider and any components rigidly affixed to it—such as a portion of the mounting springs—and any active measuring elements—such as strain gauges or the core of a linear variable differential transformer.

Since the deflection of a transducer of this basic design is limited to a small fraction of free arterial distension, the reduced force implies a reduction in the energy (blood-pressure force times transducer deflection) available to influence the transducer, and dictates the use of a sensing element that uses very little of this energy.

It was originally anticipated that a force-balance technique could be employed to measure blood-pressure force and thereby take advantage of the null properties of certain displacement-sensing devices. This could provide increased stability and decreased temperature sensitivity.

However, there is no way for a force-balance mechanism to differentiate between a force produced by blood pressure acting on the rider and a force produced by acceleration of the rider. Force balance in itself, therefore, could not decrease acceleration sensitivity. Given a blood-pressure level and rider area, the only way to reduce acceleration sensitivity is to reduce suspended mass. Any force-balance technique requires some increase in suspended mass, e.g., a magnetic coil or core for electric forcing, a plate electrode for electrostatic forcing, or a diaphragm for pneumatic forcing. As rider area is reduced, acceleration sensitivity becomes the predominant problem and the additional suspended mass required for force balancing cannot be tolerated.

It is possible to design the mass-spring-restoring force system so that the geometric arrangement results in cancellation of inertial effects. This technique was eventually employed, but could not be incorporated into a force-balance design.

The circular rider specification of 0.020 in diameter is a reasonable fit to the temporal artery and is a practical size for manufacture. An additional consideration, which limits size reduction, is that the rider diameter must not be so small that the skin surface cannot follow transducer

deflections into the rider cavity. Since actual rider and skin deflections are about 10 µin or 0.05 percent of the chosen rider diameter, this problem should not be significant. Another limitation to rider size reduction is that the rider should not be smaller than nominal skin roughness. The 0.020-in rider diameter appears to approach this limit. It may be that the transducer, if positioned over a skin crevice, would not make adequate contact with the skin surface. The choice of rider diameter gives a rider area:

$$A = \pi r^2$$

= 3.14 × 10⁻⁴ in²

A basic requirement of this transducer is that skin deflection be maintained at some small fraction of free-skin deflection. According to the specifications set forth in the previous project, we have confined transducer deflection to 10×10^{-6} inches for a 300-mmHg pressure. This fixes the spring rate of the transducer at

$$K = \frac{blood\text{-pressure force}}{displacement} = \frac{blood\text{-pressure} \times rider area}{displacement}$$

= 182 lb/in.

B. SENSING ELEMENT

A linear variable differential transformer (LVDT) was chosen as the primary sensing element. Advantages of an LVDT include the ability to measure microinch displacements, a fairly light core that decreases the suspended mass of the transducer rider assembly, and (unlike strain gauges) a signal level independent of spring geometry and strain. This allows more freedom in the choice of a mounting spring design. Some practical problems are encountered in providing adequate shielding of the LVDT coils, and in obtaining a sufficiently small unit. Commercially available units, typically designed to measure ±0.005-in displacement, have physical

coil dimensions of 1/2-in length and 1/2-in diameter with a core mass of 2.5×10^{-4} lb. Using this core weight as the suspended mass would result in an acceleration sensitivity of

acceleration sensitivity =
$$\frac{\text{acceleration effect}}{g}$$
=
$$\frac{\text{suspended weight}}{\text{blood pressure}}$$
=
$$\frac{2.5 \times 10^{-4}}{18.2 \times 10^{-4}}$$
= 0.137

which means that the transducer would produce an output 13.7 percent of full range for a 1-g change in acceleration.

Attempts to obtain smaller units specially constructed for this application resulted in the Kavlico Electronics LVDT with coil dimensions of 1/8-in length and 1/8-in diameter with a core weight of 0.093×10^{-4} lb. This small core is about equal in weight to other sprung parts—such as a rider spindle and portions of the support springs. The total suspended weight is 0.358×10^{-4} lb and acceleration sensitivity is 0.020, resulting in 2 percent of full—scale output per 1—g change in acceleration. While this is a distinct improvement, it would still result in an output equivalent to 6-mmHg blood pressure per g or an apparent change of 12 mmHg when the transducer is inverted to produce a 2-g change. While such a device might be useful for careful clinical applications, it would not fulfill that purpose of this project. Consequently, it was necessary to consider ways of compensating for inertial effects.

Inertia compensation is achieved in the latest models of blood-pressure transducer by the method illustrated in the diagram of Fig. 1. Rather than mount the LVDT coil rigidly to the transducer base plate, it is suspended on compensating spring \mathbf{k}_1 . The coil mass/spring support system is designed to have the same nominal displacement to an axial

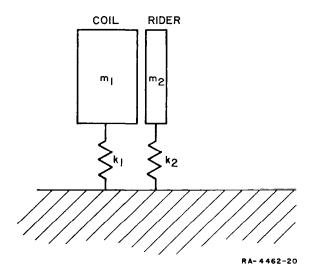


FIG. 1 TECHNIQUE FOR ACCELERATION COMPENSATION

acceleration as the rider with its spring k_2 . Thus, in theory, there is no relative displacement between coil and core and, accordingly, no output signal. In practice, it is impossible to achieve perfect matching of the two systems. The sensitivity to acceleration decreases in proportion to the difference in natural frequencies of the two spring/mass systems. (This result is derived and discussed in Appendix A.)

The general configuration of the temporal artery transducers is shown in the diagram of Fig. 2. The core of the LVDT is affixed ridigly to the arterial rider spindle. Blood-pressure force acts directly on the end of the rider spindle to deflect the rider spring diaphragms and move the core with respect to the coil. The coil is also mounted between two spring diaphragms to achieve the same natural frequency as the rider assembly. Two diaphragms are used in each core to provide lateral support and prevent twisting motions. An axial component of accelerations acts on both the coil and rider assemblies to produce nearly equal displacement and reduce their relative motion toward zero.

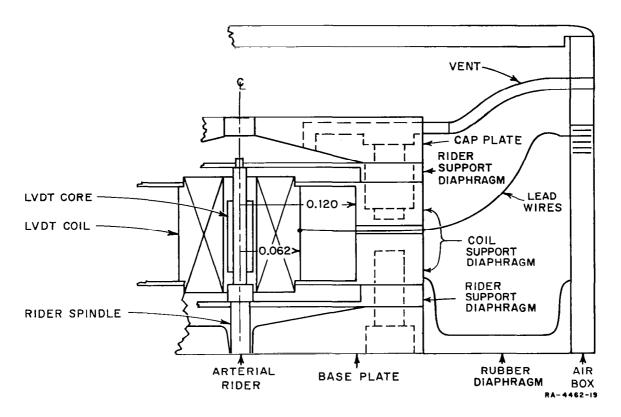
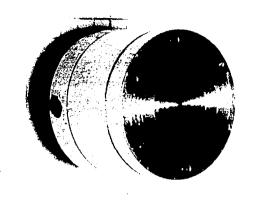


FIG. 2 CROSS SECTION OF MODEL D-2 TRANSDUCER

C. PROTOTYPE TRANSDUCERS

During the course of this project, two transducers of this general configuration were built. The first transducer (Model D-1, Fig. 3) used a large, commercially available LVDT. This was used to test the feasibility of using a 0.020-in diameter rider, the inertia compensation technique, and to gain experience in design and construction techniques for this type of transducer. The second transducer (Model D-2, Fig. 4) was essentially a scaled-down version of the Model D-1 using a smaller, specially-constructed LVDT and incorporating refinements in design details. Components and assembly of this transducer are shown in Appendix B.



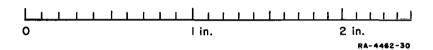


FIG. 3 PHOTOGRAPH OF MODEL D-1 TRANSDUCER

D. ELECTRONICS

The design of the equipment for measurement of the output of the differential transformer is based on the work of Wobschall.3 The circuit described was designed for the measurement of very small displacements with a differential transformer. It also had the capability of being operable over a wide range of excitation frequencies without requiring numerous adjustments within the electronic circuitry. A block diagram for this system is shown in Fig. 5. The output signal from the differential transformer is amplified in a broadband amplifier, then applied to a sensitive demodulator. The NULL potentiometer reduces the residual voltage, which occurs when the transformer core is centered between the two secondaries. A second differential transformer, mounted in the electronics cabinet and identical to the one in the transducer, supplies the reference voltage for the phase-sensitive demodulator. reference transformer core is positioned near the end of its linear range to provide the reference phase near the extreme of voltage for the differential transformer. Since the null balance voltage residual is

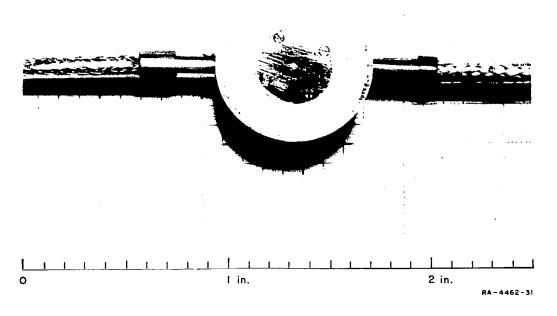


FIG. 4 PHOTOGRAPH OF MODEL D-2 TRANSDUCER

90 degrees out of phase with this extreme-end voltage, the phase-sensitive demodulator produces no output when the transducer core is at the null position; thus, the output of the electronics is proportional to the core position even through the null point. Because the output of the transducer differential transformer is a very small change in level, the gain of the broadband amplifier must be very high. It is therefore necessary to maintain a sufficiently low level of null voltage in order to avoid saturation of the amplifier; hence the inclusion of the NULL potentiometer. Since the reference amplifier and phase-sensitive demodulator are broadband units, changing the operating frequency requires only varying the audio-oscillator input frequency and readjusting the NULL potentiometer for minimum NULL voltage. Details of the circuitry for this unit are given in Appendix C.

E. ALIGNMENT AND TESTS

The transducers were tested to determine their sensitivity, signal-to-electrical noise ratio, ability to position on the temporal artery,

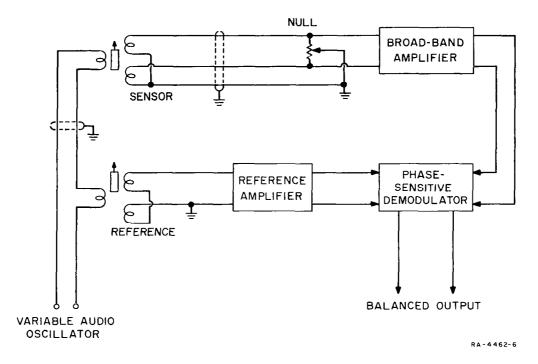


FIG. 5 BLOCK DIAGRAM OF TRANSDUCER ELECTRONICS

and acceleration sensitivity. They were operated to obtain bloodpressure measurement at the radial and temporal arteries of several individuals.

Mechanical zero adjustment of the core was accomplished by removing the rider spindle from the transducer and displacing the rider on its spindle. This was accomplished as the final step of assembly.

Before each test, electrical zero was checked to ensure that electrical null was achieved. Electrical null is evidenced by the low level of excitation frequency component in the transducer output. Figure 6 shows an oscilloscope photograph with the excitation voltage displayed on the upper trace and transducer null output on the lower trace. It is evident that most of the output signal is composed of frequency components higher than the excitation frequency. These higher frequency components are filtered by the phase-sensitive detector.

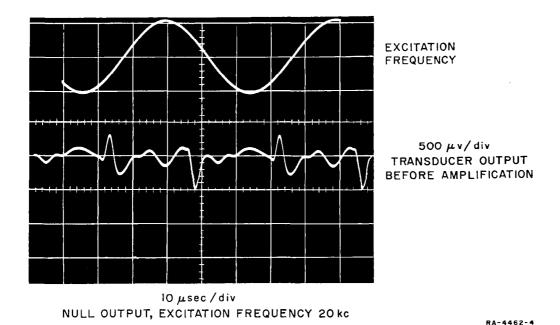


FIG. 6 TRANSDUCER OUTPUT AT ELECTRICAL NULL (Model D-1)

F. OPERATIONAL CHARACTERISTICS OF MODEL D-2

The pressure sensitivity of Model D-2 is lower than that of the earlier and larger Model D-1, while the electrical output noise level is about the same. This results from two characteristics of Model D-2. First, it was not possible to include in the miniaturized transducer a means for adjusting the zero-level core position while the transducer is in operation. This means that the core is adjusted as close as possible to the electrical center of the differential transformer by removing the rider and sliding the core on the rider shaft, each time assembling the transducer and checking the null output. Two reasons dictate that this null should be as low as possible:

- (1) The lower null voltage permits higher gain in the signal amplifiers without saturation of the output stages, and
- (2) Since null voltage increases with excitation frequency, a high frequency can be used, thus increasing the deflection sensitivity of the differential transformer.

The null position established in the present assembly permits a maximum gain of 16,000 at 30 kc. Since most of the noise present at the output is amplifier input noise, no improvements in S/N ratio would be obtained by lower null.

The second characteristic which lowers signal output is the limitation on excitation voltage with the smaller transformer. The Model D-1, using a full size differential transformer, was designed for 3v rms excitation voltage at 20 kc, while the small transformer used Model D-2 is limited to 1v rms at 30 kc. The higher excitation frequency and basically higher sensitivity of the miniature transformer compensate somewhat for the lower excitation. The performance of the two models are compared in Table I. Figure 7 shows the performance of Model D-2

Table I
CHARACTERISTICS OF PROTOTYPE TRANSDUCERS

CHARACTERISTIC	MODEL D-1	MODEL D-2
Pressure Sensitivity µv/V/mmHg		
Design Intent	0.15 @ 20 kc	0.174 @ 30 kc
Measured	0.12 @ 20 kc	0.115 @ 30 kc
Deflection, µin/100 mmHg (based of manufacturer's specification of transformer sensitivity)	3.0	2.0
Uncompensated Acceleration Sensitivity (Rider weight/B.P.)	+50 mmHg/g	+6 mmHg/g
Measured Acceleration Sensitivity	+50 mmHg/g	<2 mmHg/g
Signal to Noise Ratio,	30:1	15:1

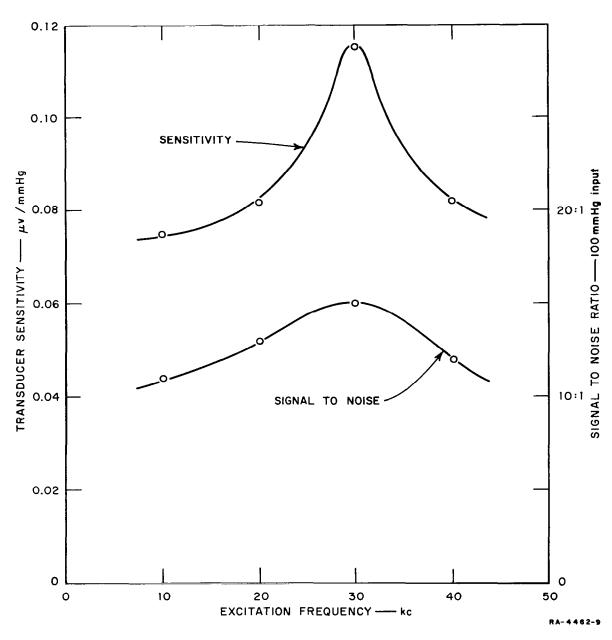


FIG. 7 PERFORMANCE OF MODEL D-2 TRANSDUCER AS A FUNCTION OF EXCITATION FREQUENCY

as a function of excitation frequency, and Fig. 8 shows the transducer response to pressure at various frequencies. (For this curve, the pressure was returned to zero before each point was taken. To determine hysteresis effects, pressure was applied in steps without returning to zero between points.) The curve of Fig. 9 shows hysteresis of approximately 10 percent, which is probably due to foreign material between the rider and side plates. For lower hysteresis, the transducer should be cleaned after each use; this, however, requires time-consuming readjustment of core null position. A very thin (less than 0.5 mil) plastic surface protection could be used, but would have to be designed for the particular transducer application being considered. Bonding of these materials to the face of the transducer has proved very unsatisfactory.

It is very important to maintain short cable leads with secure connections. The excitation and signal leads are run in separate cables. The low impedance of the differential transformer makes the system extremely sensitive to variations in cable resistance and reactance; therefore the cable should be immobilized as much as possible during application of the transducer.

Calibrated pressure waveforms were obtained from both the temporal and radial arteries with the Model D-1 indicating the validity of the design. However, pre-calibrated pulse amplitudes were not achievable with the final Model D-2. A sample record of the radial artery measured by D-2 is given in Fig. 10. The Valsalva manuever generally produces much higher amplitudes than indicated in this record. Recordings at the temporal artery are not yet obtainable with the Model D-2. Pressure applied through the calibration device, which provided the data for Figs. 6, 7, and 8, produces a clean, repeatable response from the transducer. The difficulties in getting response through a skin surface are not understood and cannot be attributed exclusively to the small rider diameter, since Model D-1 (which did perform on the skin) had the same rider size. This problem is still under investigation.

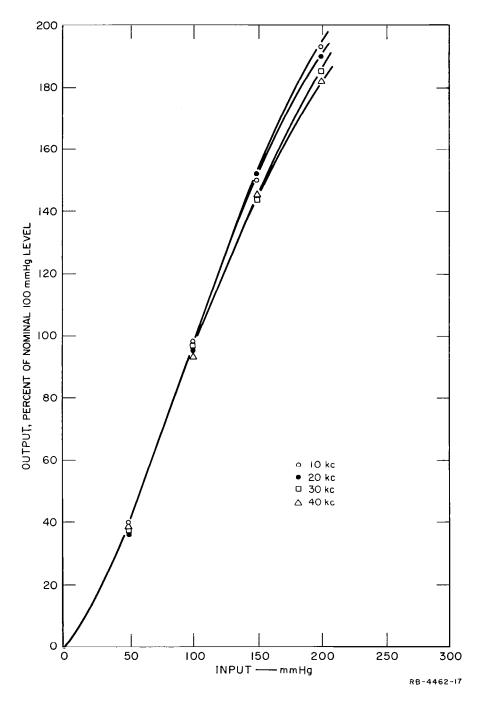


FIG. 8 TRANSDUCER RESPONSE CURVE (Model D-2)

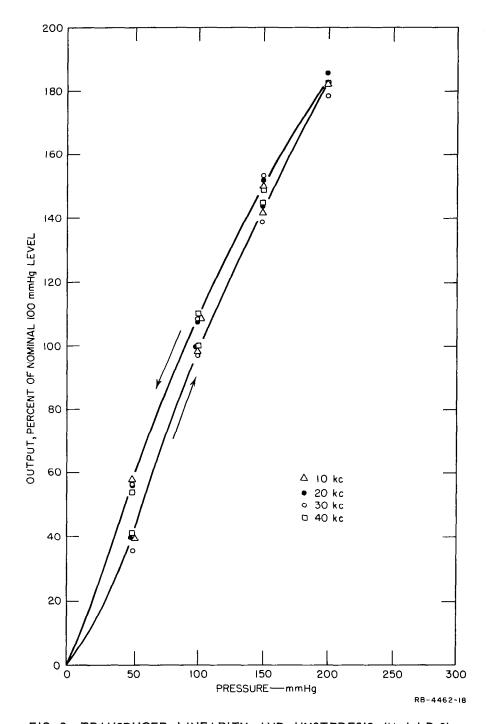


FIG. 9 TRANSDUCER LINEARITY AND HYSTERESIS (Model D-2)

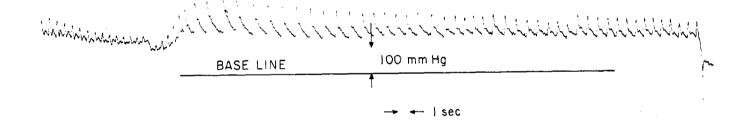


FIG. 10 BLOOD PRESSURE RECORDING FROM RADIAL ARTERY (Model D-2)

III COMPARATIVE TESTS OF THE SRI STRAIN GAUGE TRANSDUCER AND A CONVENTIONAL INTRA-ARTERIAL CANNULA SYSTEM

A. PURPOSE OF TESTS

The purpose of these tests was to determine the accuracy of the SRI strain gauge transducer developed on an earlier project measuring arterial blood pressure directly through the wall of an exposed artery. A further purpose was to determine whether or not the "artificial artery" calibration apparatus and technique allows a sufficiently accurate pre-calibration of the transducer.

Most previous evaluations has been obtained by comparison with a concurrent sphygmomanometer reading taken on the opposite arm of a human subject. These tests showed that the SRI transducer was at least as accurate as the sphygmomanometer. To define its accuracy further, comparison with a more accurate reference instrument was necessary.

Although it will be eventually necessary to perform comparative tests on human subjects, the use of animals allows considerably greater freedom to induce radical changes in blood pressure and greatly simplifies surgical preparation. In particular, dogs were chosen because of the many similarities between their cardiovascular system and that of humans. The one difficulty associated with dogs is that their major arteries are much smaller than man's; this requires the use of a more central (larger) artery than is normally used on human subjects. The central arteries of the dog are not superficial and are not supported by a rigid substructure of bone, as are the radial and temporal arteries of man. This necessitated the surgical exposure of the artery and the use of an artificial structure to support the artery. This procedure removes the skin characteristics and substructure, thereby removing potential sources of inaccuracy. The tests, therefore, demonstrate the ability of the transducer to measure through the artery wall, but give no information on ability to measure through the complete physiological

structure of an artery that is covered with tissue and skin. More complete tests would have to be accomplished on human subjects or larger animals.

B. EXPERIMENTAL TECHNIQUES

The experimental preparation used to perform the pre-calibration and comparison of external and cannula systems is shown in the diagram of Fig. 11. The connection to the dog is to the left femoral artery.

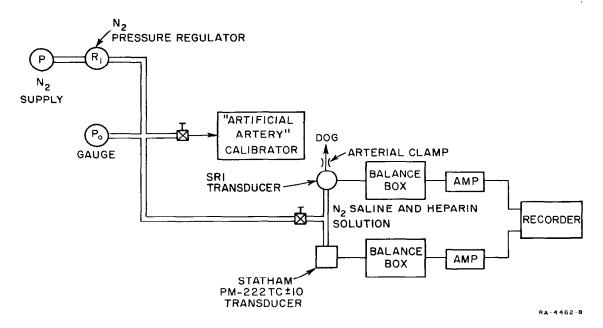


FIG. 11 BLOCK DIAGRAM OF EXPERIMENTAL PREPARATION

The SRI transducer and the reference transducer both use the same exposed section of femoral artery. It was determined that measurements performed on opposite femoral arteries did not agree because the presence of the cannula system modifies arterial pressure by the difference in loading under the two conditions. The cannula provides a rigid, dead-end load and eliminates normal variability in peripheral vascular resistance; the normal peripheral arterial system is much more compliant and allows continuous flow-through.

The reference instrument used for these tests was a commercial strain gauge transducer * connected to the arterial system through a direct intra-arterial cannula system. Its advertised accuracy and linearity of 1 percent were verified by static calibration using a mercury manometer reference.

The signals from the SRI and reference transducers were both amplified and recorded on separate channels of a Sanborn Model 320 chart recorder. The accuracy of the electronics and recorder system were within ± 2 percent over the frequency range from 0 to over 100 cps. The recorder trace could be read to about ± 0.5 mm or about 1 percent of a typical 50-mm signal amplitude.

A regulated nitrogen supply was used to pressurize the "artificial artery" for pre-calibration and to pressurize the cannula system for static comparisons of the Statham and SRI transducers.

A conventional pressure gauge such as normally used with a sphygmomanometer was used to obtain nominal pressure levels and to set the gain of the Statham transducer system. All other pressure levels were then referenced to the Statham to take advantage of its ±1 percent static accuracy.

It became apparent during early trial runs that the least accurate link in the reference system was the cannula. One form of trouble was due to the occasional development of blood clots near the cannula orifice. While the clot formed, it caused a gradual increase in resistance to flow. This, coupled with the small but still significant compliance of the cannula system, resulted in a slight decrease in pressure level—especially in the higher-frequency components. Thus, the effect of a clot was a slight decrease in pulse wave amplitude and a slight distortion of pulse waveform. Such errors were generally not detected until after a test was completed. Consequently some early runs were invalidated. Increases in heparin content and re-design of the cannula to allow convenient washout ended this form of difficulty.

^{*} Statham Instrument Co. Type PM-222~TC ± 10.

Another equally serious difficulty was in maintaining a sufficiently noncompliant chamber between the SRI transducer and the reference transducer. It was found by separate experiments that as little as one inch of flexible Tygon tubing in the cannula system is sufficient to distort the pulse wave radically, i.e., a compliant cannula system causes the pressure at the reference transducer to be much different than the pressure in the artery under the SRI transducer. By reducing the flexible portions of the cannula system to about 1/8 in of Tygon tubing and carefully purging all air from the system, it was possible to bring the two pressures into agreement within less than 5 percent for all pulse pressure frequencies up to 100 cps. Since the cardiovascular system will not impose frequencies higher than this on the cannula, this is believed to be adequate for the measurement of blood pressure. Thus, although the Statham transducer is accurate in all respects to ±1 percent, the dynamic response of a cannula system can cause much greater changes in dynamic pressure and cannula measurement cannot measure true arterial blood pressure closer than about ±5 percent. Although this is not as accurate as originally hoped, it represents an improvement over the previous sphygmomanometer reference. The latter should not be considered accurate to closer than ± 20 percent when interpreted by different individuals. In addition, the cannula reference allows dynamic comparison of the pulse waveshape.

C. EXPERIMENTAL PROCEDURE AND RESULTS

Two types of comparative tests were performed on two nominally identical models of SRI strain gauge transducers. The only differences were those of normal variations in materials and workmanship during their construction.

One transducer, designated Model S-5B, was tested on 15 dogs while changes in blood pressure were induced by injection of several drugs and by vagal stimulation. Figure 12 shows a sample data sheet used during these tests and displays the methods of calibration and the variety of stimulations used.

DATA SHEET - ANIMAL TEST

TEST NO. <u>/4</u>
DATE: <u>5 Feb. 64</u>

BY P.M. NEWGARD

PRE-RUN CALIBRATION

Set recorder gain at 10 mv level.

STATHAM REFERENCE TRANSDUCER MODEL PN-222 TC = 10

Event	Record	Mark Chart
Set zero with balance control, after catheter is filled.	Statham zero	0 mmHg
Apply 100 mmHg calibration pressure, set system gain.	100 mmHg level	100 mmHg
Return to zero, repeat above procedure if necessary.	Statham zero	0 mmHg
Set electrical calibration to match 100 mmHg level	Electrical calib	. ELEC. CALIB.

BLOOD PRESSURE TRANSDUCER MODEL 558

Event	Record	Mark Chart
Apply transducer to artificial artery. Set zero	Trans zero	0 mmHg
Apply 100 mmHg calibration pressure, set system gain.	100 mmHg level	100 mmHg
Return to zero, repeat above procedure if necessary.	Trans zero	O mmHg.
Set electrical calibration to match 100 mmHg level	Electrical calib	. ELEC. CALIB
Linearity check: Apply 0 to 250 mmHg pressure in steps of 50 mmHg to Statham and B.P. Trans. simultaneously, but preceded and succeeded by 100 mm checks.	Linearity check	Mark each step with the corresponding pressure applied.

FIG. 12 SAMPLE DATA SHEET

TRANSDUCER LOCATION: LEFT FEMORAL	artery /.O inches from REF
TRANSDUCER WARM-UP ON ARTERY	
	T. DIAL READING <u>O. 4/05</u> THERM ZERO
PRE-RUN TRANSDUCER ZERO (lift transduc zero box pre	cer momentarily with 0 mmHg.
2610 00% P1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
ANIMAL USED DOG	
ANIMAL WEIGHT 15.4 kg	
ANESTHETIC Sodium Pantaberhital	: 35 mg/kg & V time: 9:30
<u>,, </u>	
<u></u>	6 iv 11:15
TEST RUN	
MARK CHART WITH NUMBER CORRESPONDING	TO EVENT.
SWITCH TO THERMISTOR BETWEEN EACH ITE	M.
1. Acetylcholine Injection 2	_ μgm/kgm i.v.
	_ μgm/kgm 1.v.
3. First Ligation Rt. Vagus	
4. Second Ligation Rt. Vagus (cent	ral)
5. First Ligation Lft Vagus	
6. Second Ligation Lft. Vagus (cent	ral)
7. Cut right vagus	
8. Cut left vagus	
· · · · · · · · · · · · · · · · · · ·	_ μgm/kgm i.v.
0. Norepinephrine Injection <u>5</u>	_ μgm/kgm i.v.
1. Stimulate right peripheral vagus	
2. Stimulate left peripheral vagus	4 volts 5 seconds
3. Stimulate right central vagus	g volts 10 seconds
4. Stimulate left central vagus	8 volts 10 seconds
5. Bilateral Carotid Occlusion	15 seconds
6. Atropine Injection	Q.5 mgm/kgm

FIG. 12 SAMPLE DATA SHEET (Continued)

3

REPEAT SAME AS 9 THROUGH 15

17.	Acetylcholine Injection.	2 μgm/kgm 1.v.
18.	Norepinephrine Injection	
19.	Stimulate right peripheral vagus	4 volts 5 seconds
20.	Stimulate left peripheral vagus	4 volts 5 seconds
21.	Stimulate right central vagus	8 volts 10 seconds
22.	Stimulate left central vagus	A volts 10 seconds
23.	Bilateral Carotid Occlusion	15 seconds

Event	Record	Mark Chart
Record Thermistor output on chart	Therm. check	THERM
Zero thermistor (center of chart)	Therm. zero level	THERM ZERO
THERMISTOR DIAL READING 0.4282		
Check recorder calibration (10 mv level)	10 mv calib	REC. CALIB.
Set recorder zero to center of chart.	Recorder zero	REC: ZERO
Reduce air box pressure to zero, lift transducer from artery and record transducer zero	Trans. zero level	0 mmHg
Electrical calibration pulse (Transducer)	Elec. calib	ELEC. CALIB
Clamp artery, vent Statham	Statham zero	0 mmHg
Electrical calibration pulse (Statham)	Elec. calib	ELEC. CALIB
Apply 100 mmHg on artificial artery and on Statham	100 mmHg level	100 mmHg

FIG. 12 SAMPLE DATA SHEET (Concluded)

Because of the high precision required in these experiments proper operation of both systems must be ensured. Only four runs were judged to be valid comparisons of the SRI transducer and reference measuring system. The criterion for judging whether the systems were operating correctly was the similarity of waveshape (not amplitude) between the two recorded signals. It was observed that variations in pulse waveshape were invariably traceable to some difficulty with either the cannula system or the recorder.

Figure 13 shows the static calibration section of chart recorded during one run (No. 14) of this series. The values obtained from this and three other calibration runs are plotted on Fig. 14 to provide a composite static calibration curve. Examination of Fig. 14 reveals that this transducer (S-5B) is nonlinear at pressures below about 80 mmHg. Since the transducer gain was set to provide agreement at 100 mmHg, This results in a large deviation at high pressures.

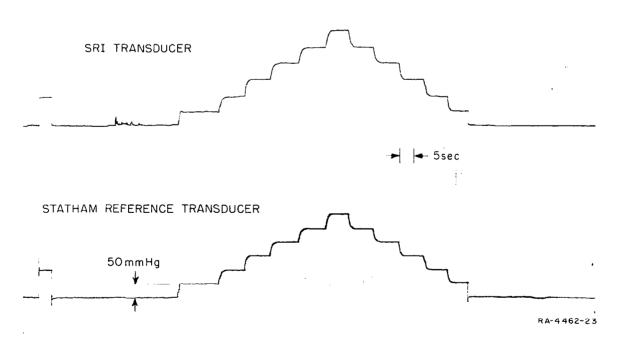


FIG. 13 STATIC CALIBRATION FOR RUN NO. 14 (Model S-5B)

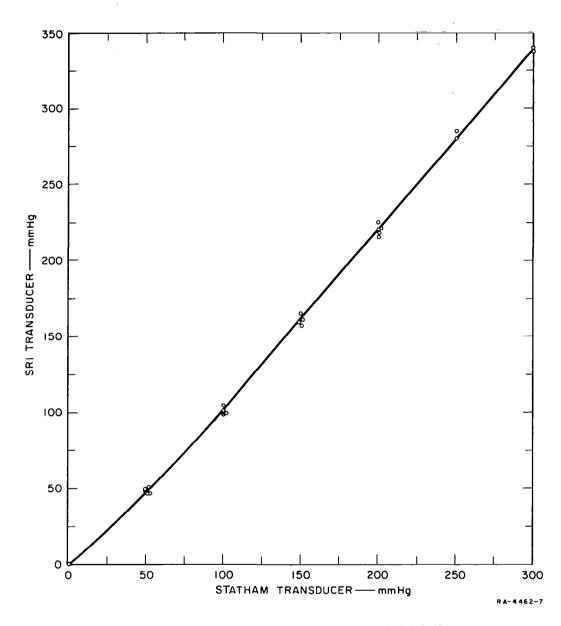
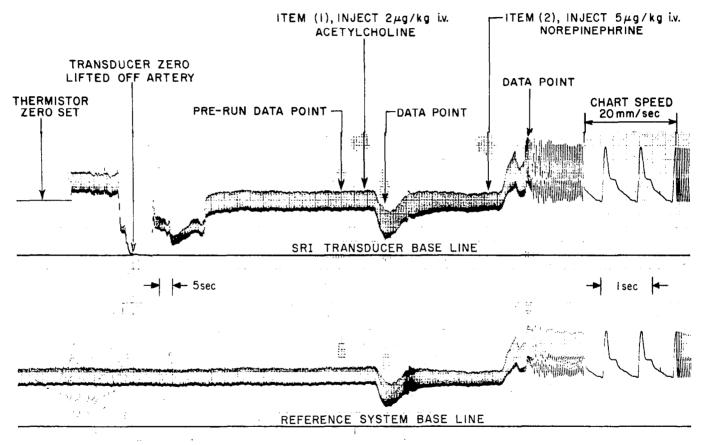


FIG. 14 STATIC CALIBRATION CURVE (Model S-5B)

Figure 15 shows various sections of recorded data from run No. 14. The first event on Fig. 15(a) shows an interruption of blood-pressure recording to obtain a measurement of transducer temperature. The temperature measurement trace was set to the center of the chart. Later, during the run, the temperature is again recorded and base line shift is adjusted accordingly. The next significant event on Fig. 15(a) is the transducer zero set. During this procedure, the SRI transducer is lifted away from the artery to allow atmospheric pressure to the arterial rider. The output at that time is set to the nominal base line position, 5 mm from the edge of the chart. The next event shows the position of the first data point used for transducer comparison. (Each data point consists of systolic and diastolic readings from simultaneous pulse pressures on both the SRI and Statham transducers.) This is taken before any manipulation is applied to the animal and is called "pre-run" The time of the first chemical alteration of blood pressure by acetylcholine is next noted. This is followed by the expected decrease in blood pressure. The second data point is taken at the time of maximum pressure change. All data points are chosen in this manner to compare the maximum pressure changes produced by each physiological manipulation of the cardiovascular status.

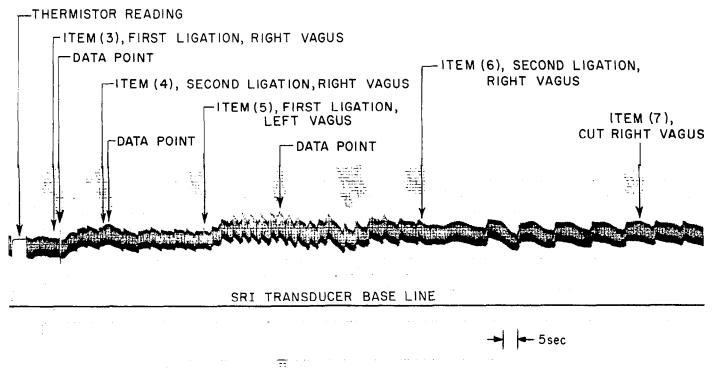
An injection of norepinephrine (Item 2) is the next significant event. This produced an increase in both mean and pulse pressures and a compensatory reduction in heart rate following the initial cardiovascular excitation. Chart speed was momentarily increased to examine and compare dynamic pressure waveshapes. The nonlinearity of the SRI transducer results in an apparent discrepancy in pulse amplitude, but the good similarity of waveshape under these conditions shows that the SRI transducer has adequate frequency response.

Figures 15(b) through 15(d) show the method of choosing data points for comparison. Figure 15(e) shows the post-run procedure. After the manipulations are completed, transducer temperature is recorded. It may be noted from Fig. 15(e) that the temperature trace has moved +5 mm from its pre-run position. Recorder zero and calibration were then



RA-4462-26

FIG. 15(a) DATA FROM RUN NO. 14



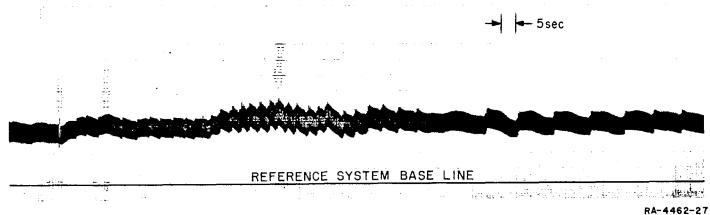


FIG. 15(b) DATA FROM RUN NO. 14

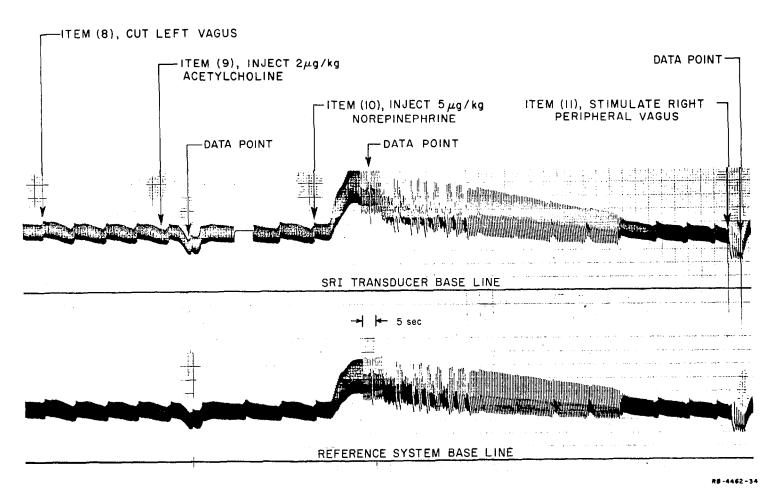


FIG. 15(c) DATA FROM RUN NO. 14

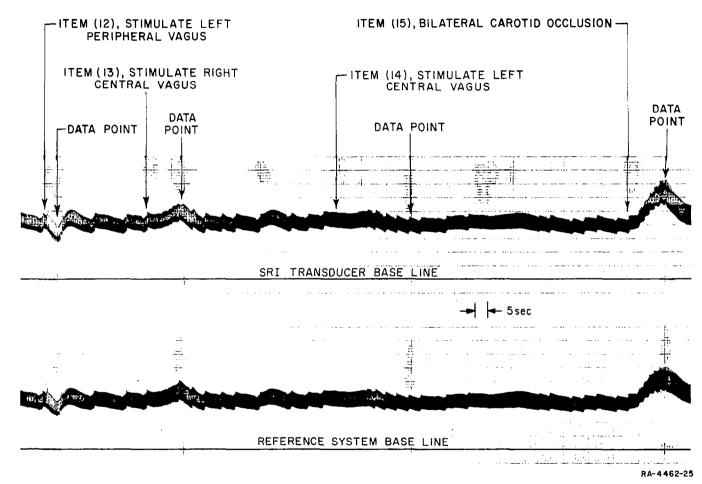
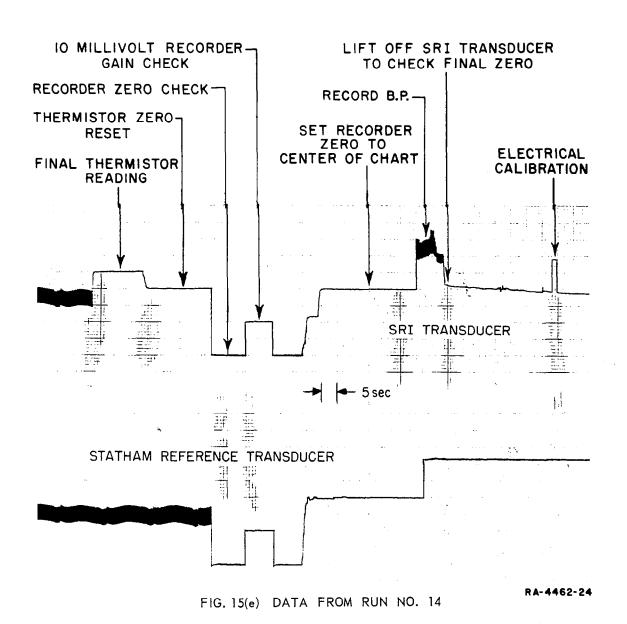


FIG. 15(d) DATA FROM RUN NO. 14



checked and (in this particular run) were found to agree with the prerun conditions. Recorder zero was then set to the center of the chart
and blood pressure recorded for a few cycles. To obtain the post-run
zero, the SRI transducer is lifted from the artery to establish atmospheric
pressure against the transducer face. It may be noted that the transducer
zero has shifted about 1 mm (10 mmHg pressure) from the recorder zero
position. Relating this to the transducer temperature variation provides
a temperature correction coefficient of 10 mmHg/5 mm or 2 mmHg per mm of
temperature trace deviation.

D. SAMPLE OF DATA REDUCTION

Since we wish primarily to determine the validity of the basic theory used to design the SRI transducer, it is necessary to modify the data to compensate for zero shift and nonlinearities.

Original data are read from the recording. For example, from Fig. 15(b), the data point following Item 3 of the test is read as follows:

SRI Systolic = 245 mmHg SRI Diastolic = 139 mmHg Reference Systolic = 214 mmHg Reference Diastolic = 122 mmHg.

The reference readings are not modified. SRI zero level is first changed to account for the +2 mm deviation of transducer temperature recorded just prior to Item 3. Using the temperature correction coefficient of 2 mmHg per mm temperature deviation results in the apparent pressure levels:

SRI Systolic = 245 - 4 = 241 mmHg SRI Diastolic = 139 - 4 = 135 mmHg.

Further correction (for transducer nonlinearity) is required. The correction is read directly from the static calibration curve of Fig. 14, yielding final corrected values of:

SRI Systolic = 217 mmHg SRI Diastolic = 128 mmHg. These values, along with all such data points from Runs 4, 10, 12, and 14 are plotted in Fig. 16. The scatter of data on Fig. 16 is due both to inherent inaccuracies of the two measuring systems and to any influence of artery elasticity. Data points showing blood pressure above 300 mmHg are included for reference but it should be noted that the static calibration was not extended beyond 300 mmHg. These points were adjusted by extrapolating the calibration curve.

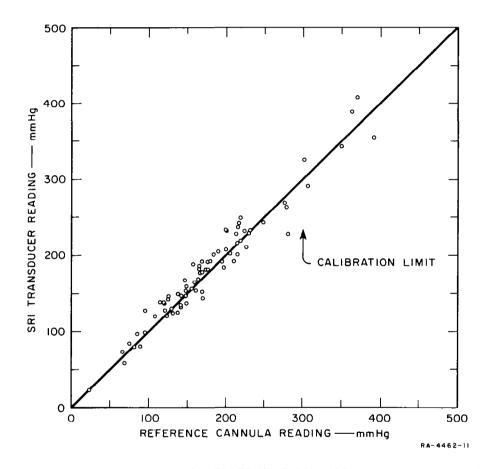


FIG. 16 PLOTTED DATA POINTS FROM RUNS NOS. 4, 10, 12, AND 14

The second transducer, designated Model S-5A, was tested by a different procedure. Some of the data from Run 19 are included on Figs. 17, 18, and 19 to illustrate the procedure. Figure 17 shows the static calibrations of the transducer on the "artificial artery" calibrator. Figure 18 shows another static calibration but with the SRI transducer

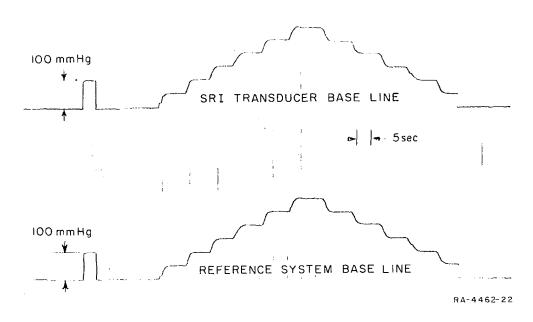


FIG. 17 STATIC CALIBRATION WITH TRANSDUCER ON ARTIFICIAL ARTERY

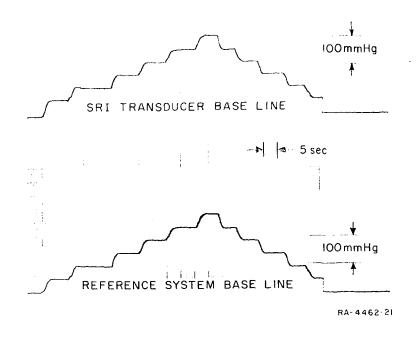


FIG. 18 STATIC CALIBRATION WITH TRANSDUCER ON ARTERY IN VIVO

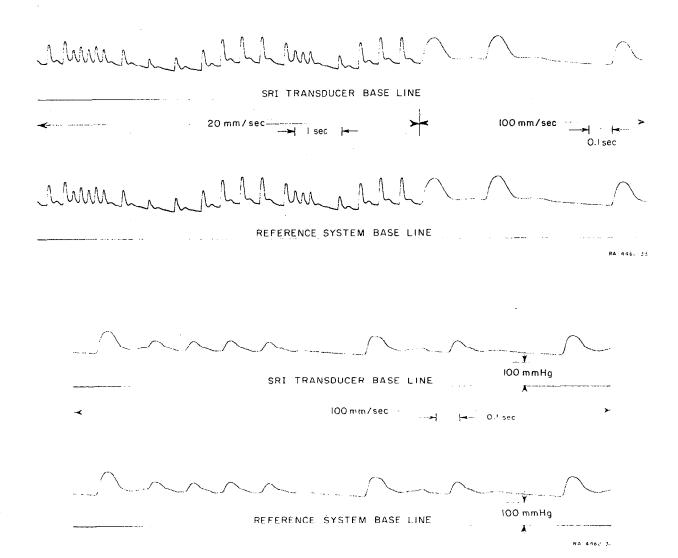


FIG. 19 DYNAMIC PRESSURE RECORDING

in place on the living artery. To obtain this data, the artery was clamped off up-stream from the transducer and opened to the cannula. Thus, the nitrogen pressure used to pressurize the cannula was also coupled into the artery through the heparin and blood solution. The clamp was then removed and arterial pressure allowed to excite both transducers. Figures 19(a) and (b) show the dynamic pressure as recorded by the two systems during a period of cardiac irregularities. The recorder was operated at various speeds, as noted on the figures.

Nineteen data points were selected at arbitrary intervals to provide a distribution of blood pressure levels.

Figure 20 shows the three sets of data obtained from Run 19. One set is from the static calibration on the "artificial" artery. Another set is from the static calibration on the living artery, and the third set represents the dynamic pressure levels recorded while the cannula was open to the dog's vascular system.

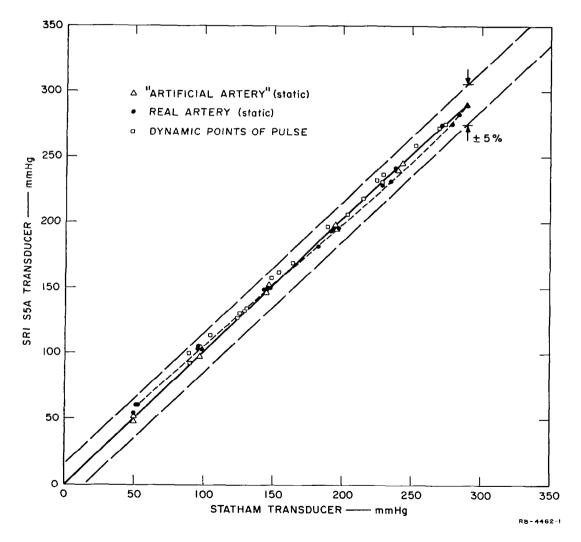


FIG. 20 DATA FROM RUN NO. 19

It may be noted from Fig. 20 that the linearity of this particular SRI transducer is within 1 percent, so that no correction for linearity was necessary. Also, since the transducer has much better temperature compensation, it was not necessary to correct its zero level. The points shown on Fig. 20 therefore are not modified in any way. The dashed lines showing ±5 percent of full-scale error are included to show that none of the data points exceed this value.

E. SUMMARY OF TEST RESULTS

It may be concluded from the above data that the "artificial artery" calibration apparatus and technique allows a sufficiently accurate pre-calibration of the SRI external transducer.

The tests show that the two examples of transducer design are reasonably similar in response and are probably representative of this design.

The recorded blood pressure as measured by the two methods are in reasonable agreement. The actual errors (assuming a completely accurate reference instrument) are ± 5 percent of Model S-5B and ± 3 percent for S-5A.

Although this device is not intended for measurement using the exposed artery, the general experience obtained during these tests indicate the following:

- (1) It is easier to obtain a measurement of arterial blood pressure in an exposed artery using the SRI transducer than it is when using the intravascular cannula reference system.
- (2) No difficulties with clotting and air bubbles are experienced.
- (3) The presence of the external transducer does not modify the arterial pressure to the same degree as does the cannula system.

A second series of experiments were performed using the Model S-5B transducer. In this test, the equipment was operated by personnel from the Life Sciences. Engineering personnel did not attend these experiments. The results obtained (summarized in Fig. 21) are similar to those given above, and provide an independent check of the earlier data.

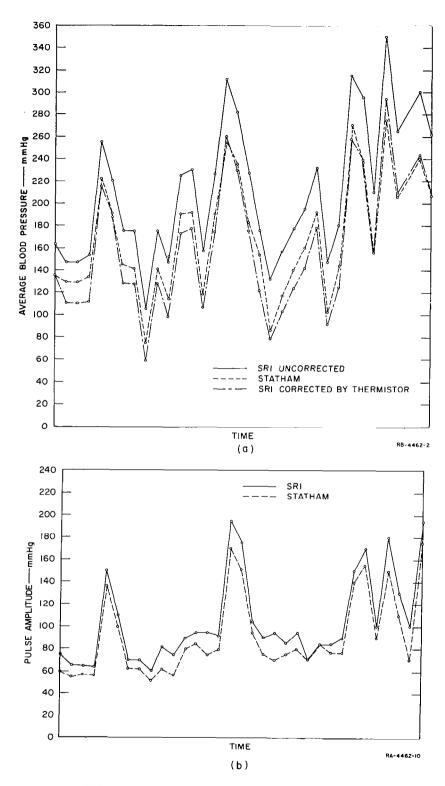


FIG. 21 DATA FROM ADDITIONAL TEST

- (a) Mean blood pressure
- (b) Pulse amplitude

IV STUDY OF POSITION-SENSING TECHNIQUES

One of the most serious problems in the continuous application of the indirect blood pressure transducer is the maintenance of the proper position over the superficial artery. Accordingly, a study was made of possible methods of sensing the artery location. Such a sensor could be used to indicate when the transducer was off position, and, depending on the quality of the output of the sensor, the transducer could be repositioned either manually, remotely, or automatically. Four techniques were considered as approaches to the position-sensing problem (see Fig. 22). These were:

- (1) Pressure-sensitive paint,
- (2) Measurement of skin impedance,
- (3) Measurement of local skin temperature, and
- (4) Use of piezoelectric force sensors.

Pressure-sensitive paints can be made with a high sensitivity to changes in force levels. Such compounds do not have stable calibrations and cannot be used as transducer elements for blood pressure measurement. However, as indicators for relative pressures in the region surrounding an artery, it was thought that such paints might be ideal. The paint is easy to use and requires almost no mechanical modification in the transducer design. A spot of paint could be placed on each side of the arterial rider; when the resistances of the paint spots were equal, the transducer would be centered over the artery. Prototype models of pressure-sensitive-paint artery sensors were constructed and tried. It was determined, however, that although the paints have a high sensitivity to changes in pressure, they are not suitable for use at very low pressure, since the drift rate and instability are very high.

Because conductivity of tissue is affected by the presence of blood, it was felt that artery position could possibly be sensed by means of an impedance probe. Tissues surrounding an artery should have a higher impedance than an artery itself; therefore, surface measurement of

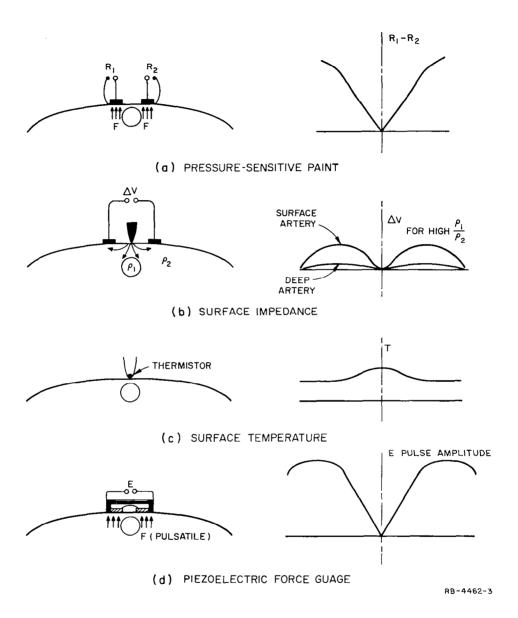


FIG. 22 POSITION-SENSING TECHNIQUES

impedance near a superficial artery might show distinct changes in the locale immediately over the artery. A number of location-sensing electrode configurations were conceived and checked experimentally on conductive paper. The most sensitive configuration was incorporated into an artery sensor probe. However, it was not possible to obtain a clear indication of the artery position with this probe. High-frequency currents were used in order to avoid skin contact resistance and contact potentials, which would tend to mask resistance variations beneath the surface. Apparently, the conductivity of the artery is not significantly higher than that of the surrounding tissues. Perhaps more sensitive or elaborate probe systems could be designed to detect the presence and position of the artery; however, for the position-sensing purpose it is necessary ot obtain the signals with minimum complexity and difficulty and this approach was not considered further.

The possibility of an increase in skin temperature directly over the artery was considered. Measurements were made with a sensitive thermistor probe and no temperature differences were clearly distinguishable. It is probable that, even if slight temperature differences did exist, the thermal mass of the pressure transducer resting over the skin surface would tend to eliminate them. Therefore, this approach was only considered very briefly.

Finally, the technique of force sensing by miniature piezoelectric elements constructed into the transducer was studied. Although this approach would require greater construction complexity for an eventual transducer than any of the previously tried methods, the ability of crystal sensors to detect the arterial pulse was well established by earlier experiments. A position sensor consisting of two barium titanate beams was constructed [see Fig. 22(d)]. The beams are connected so that the signals produced by the pulsating pressure are in opposition. Therefore, if the artery is centered between the two beams, the net output is zero; any movement of the transducer from the artery results in either a positive or a negative pulse wave, depending on the direction of shift with respect to the artery. A position sensor was constructed using

these elements and experiments indicated a satisfactory output and high sensitivity to position over the artery. Such a device would be more than adequate for the determination of the arterial rider position.

Because the crystals only respond to the variational pressures, i.e., the pulse wave, corrections to the position of the transducer are limited to the pulse rate. This may make application of this technique to an automatic-position-restoring mechanism very difficult, especially if a shock or other rapidly changing condition causes sudden movement of the transducer. However, as an indicator for proper manual positioning, this technique should be satisfactory.

APPENDIX A

ALLOWABLE DIFFERENCE IN RESONANT FREQUENCY BETWEEN COIL AND CORE DIAPHRAGMS

The resonant frequency of a spring-mass system is

$$f = \frac{1}{2}\pi \frac{k}{m};$$

The displacement of such a system when accelerated at 1 g is $\delta = \frac{mg}{k}$. Therefore

$$f = \frac{1}{2}\pi \frac{g}{\delta}$$

or

$$2\pi f = \frac{g}{\delta}$$

and

$$\delta = \frac{g}{4\pi^2 f^2} \qquad . \tag{A-1}$$

for the rider: $\delta_g = \frac{g}{4\pi^2 f_r} \; , \quad \text{where } f_r = \text{resonant frequency of the}$ rider system;

for the coil: $\delta_g = \frac{g}{4\pi^2 f_c} \; , \quad \text{where } f_c = \text{resonant frequency of the} \\ \text{coil system.}$

Let $\delta_g = \delta_g - \delta_g$. Ideally, $f_r = f_c$; for this condition $\delta_g = \delta_g$ and $\delta_g = 0$. The acceleration sensitivity of the transducer is

$$S_{g} = \frac{\delta_{g}}{\delta_{t}} \quad (mmHg/g) \qquad , \qquad (A-2)$$

where δ_t is the transducer sensitivity in terms of deflection per mmHg. For perfect matching of f and f , S = 0; for imperfect matching

$$S_g = \frac{\delta_g - \delta_g}{\delta_t}$$

$$S_g = \frac{g}{4\pi^2 \delta_t} \quad (\frac{1}{f_c} - \frac{1}{f_r})$$
 (A-3)

If we assume $f_r = f_c + \Delta f$, where $\Delta f \ll f_c$, then

$$S_{g} = \frac{g}{4\pi^{2}\delta_{t}} \frac{1}{f_{c}^{2}} - \frac{1}{f_{c}^{2} + 2f_{c} \Delta f}$$

$$s_g = \frac{g}{4\pi^2 \delta_t f_c^2} - 1 - \frac{1}{1 + \frac{2\Delta f}{f_c}}$$
 (A-4)

Since $\frac{2\Delta f}{f_c} \ll 1$,

$$S_{g} \approx \frac{g}{4\pi^{2}\delta_{t}f_{c}^{2}} \qquad 1 - 1 + \frac{2\Delta f}{f_{c}} \qquad = \frac{g}{2\pi^{2}\delta_{t}} \frac{\Delta f}{f_{c}^{3}}$$
 (A-5)

The required Δf for given S_g is then

$$\Delta f = \frac{2\pi^2 \delta_t f_c^3 S_g}{f_c^9}$$
 (A-6)

for
$$f_c = 5,000 \text{ cps}$$

$$S_g = 1 \text{mmHg/g}$$

$$\delta_t = 3 \times 10^{-8} \text{ in/mmHg}$$

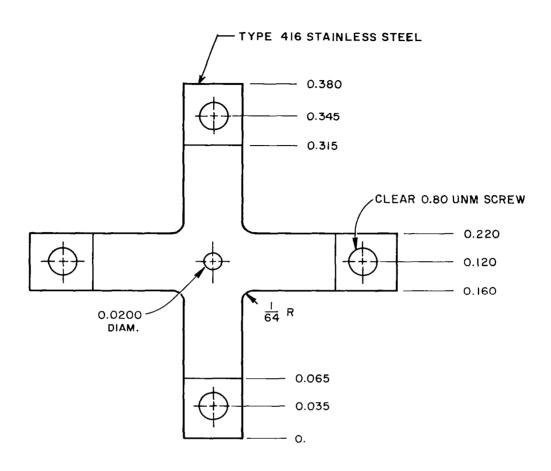
$$\Delta f = 2\pi^2 \times 3 \times 10^{-8} \ 125 \times 10^9 \times 1 \times \frac{1}{386}$$

$$\Delta f = \frac{750}{386} \times 10^2$$

$$\Delta f = 190 \ \text{cps}$$
 .

APPENDIX B

COMPONENTS OF MODEL D-2 TRANSDUCER



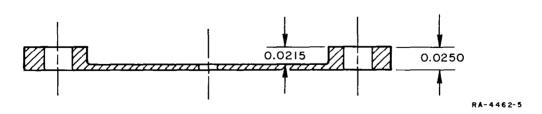


FIG. B-1 RIDER SUPPORT DIAPHRAGM

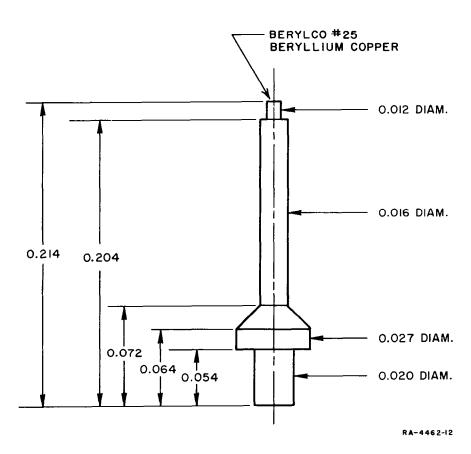
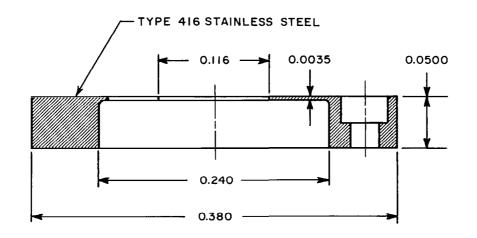


FIG. B-2 RIDER



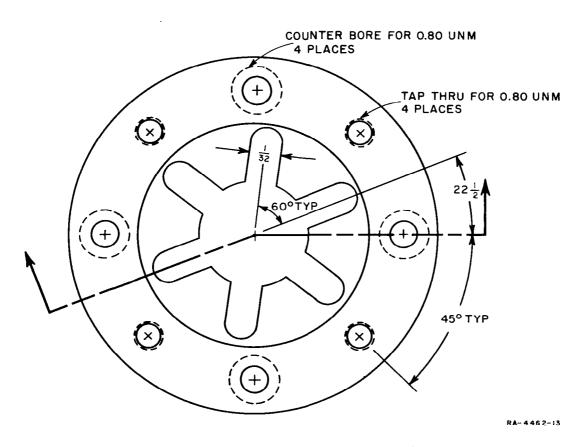
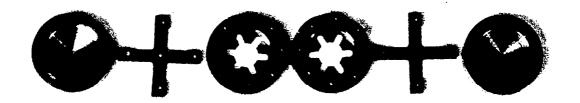


FIG. B-3 COIL SUPPORT DIAPHRAGM



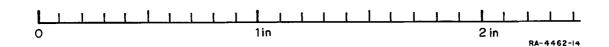


FIG. B-4 MODEL D-2 TRANSDUCER COMPONENTS

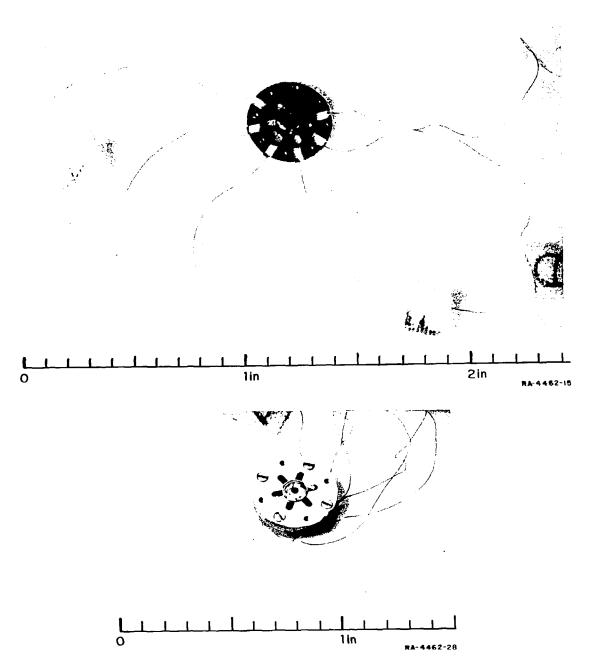


FIG. B-5 TRANSFORMER COIL MOUNTED IN SUPPORT DIAPHRAGM





FIG. B-6 ASSEMBLED TRANSDUCER

APPENDIX C

DEMODULATOR DESIGN

The demodulator package consists of two amplifiers, a phase-sensitive demodulator circuit, and metering circuits for excitation and output voltages (Fig. C-1). Signal amplifier (Card A) receives the signal from the differential high-gain amplifier (not included in the demodulator equipment) and amplifies this signal to approximately lv p-p at a dc level of 10 to 15v, as required by the phase-sensitive demodulator. The second amplifier (Card B) receives the signal from the reference differential transformer, which is a separate plug-in unit. Since the reference transformer core is set near peak output, the gain of the amplifier on Card B need not be as great as the Card A amplifier, However, the amplifier on Card B includes a phase-inverter circuit, which provides two outputs with 180 degrees phase difference and both outputs at approximately zero average level. The output voltage of the reference amplifier is approximately 3v p-p. The magnitude of the reference voltage is adjusted by positioning the core in the reference transformer. The dc levels and relative amplitudes of the outputs are adjustable by trimmer resistors in the circuit--these controls should be adjusted so that the outputs of the reference amplifier are equal in magnitude and dc level. A feedback circuit using Zener reference diodes is used to maintain constant average output level without the use of coupling capacitors. Both signal amplifier and the reference amplifier are designed to be usable over a range of 100 to 20,000 cps, without significant phase shift.

The phase-sensitive demodulator circuit (Card C) is a nonreactive demodulator using switching techniques to provide an output proportional to the in-phase component of the signal voltage. The output of the demodulator is sent through an adjustable RC filter to eliminate the reference frequency components in the output. The output signal is balanced with respect to ground and must be fed into a differential-input device. The BALANCE potentiometer for the demodulator is adjusted

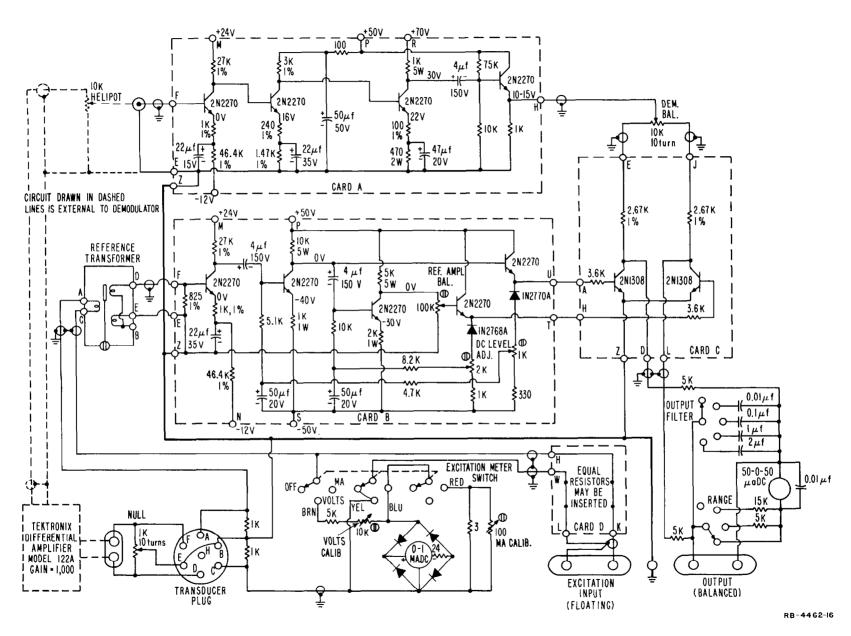


FIG. C-1 SCHEMATIC DIAGRAM, DEMODULATOR

for zero output with the input of the signal amplifier shorted. The OUTPUT meter on the front panel is used for this purpose; when the output signals are to be displayed on another device, the panel meter should be turned OFF to avoid loading the demodulator output.

The excitation for the transducers and reference transformer is provided by a separate oscillator (not included in the demodulator equipment) and fed into the excitation input. A metering circuit is provided to read the combined voltage across both differential transformer primaries, or the current through the primaries. It is desirable to provide as high an input voltage as possible to the input terminals. Series resistors may be inserted in Card D to reduce the voltage to the magnitude required by the differential transformers. The use of high input voltages and high series resistances provides essentially constant current excitation to the transformers, and results in a lower temperature sensitivity. Because of the low impedance of the reference transformer and measuring differential transformer used in Model D-2, an output impedance of 600 ohms in the excitation oscillator is sufficient to reduce the excitation voltage at the transformers by about 30:1. fore, no resistors are included in Card D for use with Model D-2 differential transformer transducer and the Hewlett-Packard Model 200 audio oscillator. However, Model D-1 did require additional resistances when used with this oscillator. The excitation input must be floating with respect to ground so that the differential transformer in the transducer will be operating with its primary balance with respect to ground potential. This balance is provided by the two 1000-ohm resistors shunting the transducer primary. The 1000-ohm 10-turn potentiometer across the transducer secondary is the NULL potentiometer and is to be adjusted for minimum null voltage as indicated at the transducer output or at the output of the differential amplifier.

Power supply voltages for the demodulator unit are provided by two plug-in power supplies, one providing $\pm 50v$, the other $\pm 70v$. Voltages for the input stages of both the reference and signal amplifiers are provided by Mercury cells mounted at the rear of the demodulator unit.

These voltages must be turned on at the rear of the unit before the demodulator will operate.

The front, front open, and rear views of the package are shown in Figs. C-2 through C-4, respectively.

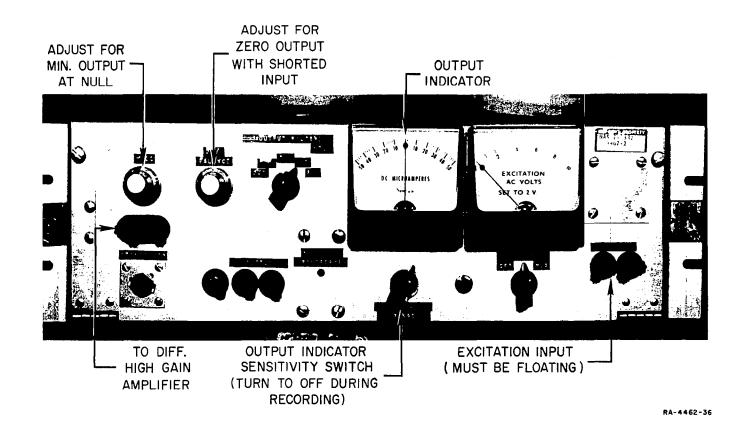


FIG. C-2 FRONT VIEW OF DEMODULATOR

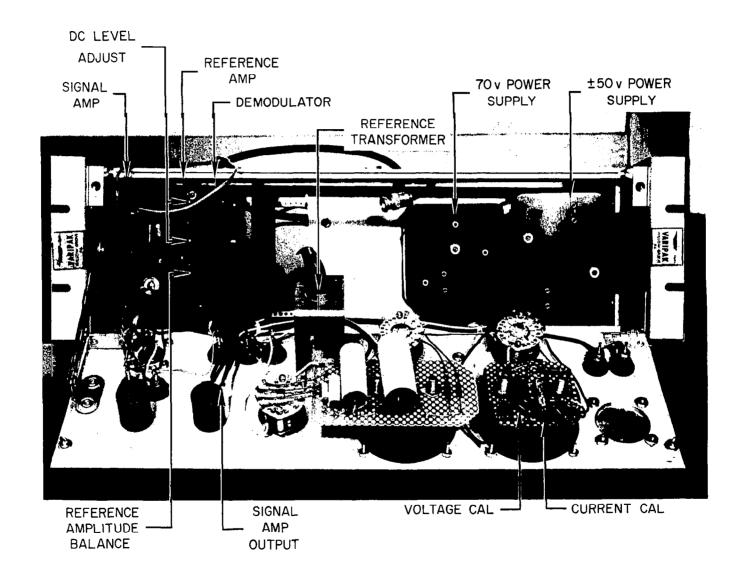


FIG. C-3 FRONT-OPEN VIEW OF DEMODULATOR

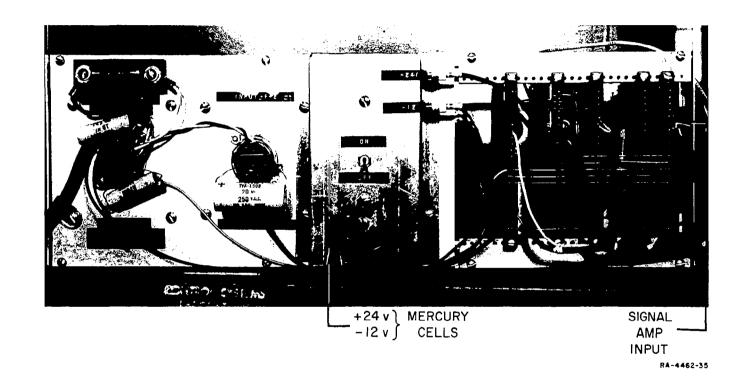


FIG. C-4 REAR VIEW OF DEMODULATOR

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